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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	March 4, 2004
Submitter:	Hach Company/Environmental Test Systems
Address:	23575 County Road 106 Elkhart, IN 46514 U.S.A. (219) 262-2060
Contact:	David A. Morris, Ph.D. Director of Technology
Device Trade/ Proprietary Name:	SteriChek® Glutaraldehyde Reagent Strips
Device Common Name:	Glutaraldehyde Reagent Strips
Classification Name:	Class II CH
Predicate Device:	Serim™ Glutaraldehyde Test Strips
Device Description:	The device is made up of a 0.20 inch square light red reagent pad that has been chemically treated to test the concentration of Glutaraldehyde in solutions for disinfecting dialyzers used in Hemodialysis. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.
ntended Use:	SteriChek Glutaraldehyde Reagent Strips provide a convenient means of testing the concentration of Glutaraldehyde in dialyzer disinfecting solutions. The test is not intended to replace microbiological tests or quantitative determinations of concentrations of stock solutions of Glutaraldehyde. The test may be used on a random sample of reprocessed dialyzers in order to document the presence of the agent during storage. SteriChek Glutaraldehyde Reagent Strips do not measure residual levels of Glutaraldehyde.

Technological Characteristics:	The device is a qualitative reagent strip method to measure Glutaraldehyde solution by color change caused by the sample on a pad containing dry reagents and indicators. Glycine in the reagent pad reacts with Glutaraldehyde and releases acid. The resulting pH change is detected with a colorimetric indicator. The active components are the pH indicator Methyl Red (CAS #845-10-3), and Glycine (CAS #56-40-6).
Assessment of Performance:	The performance characteristics of SteriChek Glutaraldehyde Reagent Strips are based on analytical studies using samples of Glutaraldehyde solutions of various concentrations. The reference method for determination of Glutaraldehyde is based on the reaction of Glutaraldehyde with hydroxylamine hydrochloride followed by titration of the released acid (Aldrich Chemical Company, "Basics Assay Method for Determination of Aldehydes and Ketones".)
Conclusion:	The SteriChek® Glutaraldehyde Reagent Strips have the same intended use as the predicate device. The predicate device's indicator system is different than that of the SteriChek Glutaraldehyde Reagent Strips. However, both systems effectively measure the pH or hydrogen ion concentration. The SteriChek® Glutaraldehyde Reagent Strips have no technological characteristics that raise new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. David A. Morris
Director of Technology
Hach Company/ETS
23575 County Road 106
Elkhart, Indiana 46514

Re: K040660
Trade/Device Name: SteriChek® Glutaraldehyde Reagent Strips
Regulation Number: None
Regulation Name: None
Regulatory Class: II
Product Code: LIF
Dated: October 25, 2004
Received: October 28, 2004

Dear Dr. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K040660

Device Name: SteriChek® Glutaraldehyde Reagent Strips.

Indications for Use:

SteriChek® Glutaraldehyde Reagent Strips provide a convenient means of testing the concentration of Glutaraldehyde in dialyzer disinfecting solutions. The test is not intended to replace microbiological tests or quantitative determinations of concentrations of stock solutions of Glutaraldehyde. The test may be used on a random sample of reprocessed dialyzers in order to document the presence of the agent during storage. SteriChek® Glutaraldehyde Reagent Strips do not measure residual levels of Glutaraldehyde

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040660